

REMARKS

The present invention relates to certain antibiotics AA-896, which are useful as antibacterials.

Claims 23, 31, 33, 40, 41, 87-93, 99, and 104-111 are pending in the application.

By the current amendment, claims 23, 31, 33, 40, 41, 87-93, 99, and 104 have been amended.

The Examiner has rejected claims 87-93 under 35 U.S.C. 101. Applicants thank the Examiner for the suggestion of the terminology "isolated" to overcome the rejection and in response, applicants have amended claims 87-93 to add the suggested terminology "isolated" and respectfully ask the Examiner to reconsider the rejection and allow the claims.

In further reply, and in addition to the March 3, 2005 office response applicants have further amended claims 87-93 to clarify that the mutants described therein are capable of producing AA-896 antibiotics. Additionally, said amended claims overcome the Examiner's rejection that the term "antibiotics" means any antibiotic including antibiotic A-32256 produced as described in US Pat. No. 4,316,959 and Cepharmycin C produced as described in US Pat. No. 4,332,891 as cited by the Examiner.

The Examiner has further rejected claims 87-93 under 35 USC 102(b) as anticipated by or, in the alternative, under 35 USC 103(a) as obvious over Michel et al (US Patent No. 4,316,959) or Kamogashira et al (US Patent No. 4,332,891). As set forth by the Examiner in the September 3, 2004 office communication, each of Michel et al and Kamogashira et al disclose a microorganism Streptomyces and the claimed microorganisms are anticipated or obvious over Michel et al and Kamogashira et al. As further described by the Examiner, if there are any differences between the claimed microorganisms and the references microorganisms, the differences would appear to be minor in nature and the claimed microorganisms, which fall within the

scope of the prior art's disclosure, would have been prima facie obvious to a person having ordinary skill in the art at the time the instant invention was made. As additionally described by the Examiner applicants have failed to point out how the claimed microorganisms differ from the references' strains.

Applicants in answer to the Examiner's statements regarding said *Streptomyces* microorganisms have provided an affidavit under 37 CFR 1.132 from VALERIE S. BERNAN which establishes that the *Streptomyces* spp. microorganisms described in US Pat. No. 4,316,959 (NRRL 12067) and as described in US Pat. No. 4,332,891 (ATCC 31666) can be distinguished from the *Streptomyces* strain LL-AA896 of the instant invention using 16S rDNA sequence analysis. The 16S rDNA sequence analysis results are presented in Exhibit 1.

The 16S rDNA sequence analysis is used to construct phylogenetic trees for comparison of genus and species. The 16S rDNA is amplified, sequenced, and the multiple sequence alignments are compared to each other and all sequences in the GenBank database. The result is a phylogenetic tree that clusters closely related species together in the same clad in the branches of such phylogenetic trees and differentiates them from unrelated species.

The molecular systematic evidence provided by the 16S rDNA sequence analysis testifies that the claimed microorganism LL-AA896 is readily distinguishable from *Streptomyces* spp. ATCC 31666 and NRRL 12067. The phylogenetic tree as presented in Exhibit 1, constructed with the 16S rDNA sequences, clearly demonstrates that *Streptomyces* spp. NRRL 12067, ATCC 31666, and LL-AA896 cluster in 3 distinct clads and are 3 distinct bacterial species from each other and not taxonomically related.

Applicants believe they have provided ample evidence that claims 87-93 are not under 35 USC 102(b) as anticipated by or, in the alternative, under 35 USC 103(a) as obvious over Michel et al (US Patent No. 4,316,959) or Kamogashira et al (US Patent No. 4,332,891). Applicants believe that the present invention is patentable over the cited references in view of the above remarks, affidavit and amendments to claims 87-93. Applicants respectfully ask the Examiner to reconsider and remove the 35 USC 102(b) and 35 USC 103(a) rejections and allow claims 87-93.

The Examiner has rejected under 35 USC 112 first paragraph, claims 23, 31, 33, 40, 41, 87, 99, and 104 as failing to comply with the written description requirement. According to the Examiner the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the Examiner's rejection the terminology "or an antibiotic producing mutant thereof" is not described or disclosed by the specification as originally filed and the term "an antibiotic" encompasses any antibiotics, including those not described by the instant specification. In response, applicants have amended claims 23, 31, 33, 40, 41, 87, 99, and 104 to redefine the terminology in the phrase "or an antibiotic producing mutant thereof" to "or an AA-896 antibiotic producing mutant thereof" to overcome the rejection. Applicants find support throughout the specification and in particular on page 18, lines 5-6 of the originally filed specification that certain AA-896 antibiotics of the invention are produced by fermentation of mutant derivative strains of *Streptomyces spp.* LL-AA896 (LL4774). Further, to overcome the terminology "an antibiotic" the amended claims describe that only AA-896 antibiotics are formed.

Applicants respectfully ask the Examiner to reconsider the rejection and allow claims 23, 31, 33, 40, 41, 87, 99 and 104 in view of the above described amendments.

The Examiner has also rejected under 35 USC 112 first paragraph, claims 23, 31, 33, 40, 41, 87, 99, and 104 as failing to comply with the enablement requirement. The terminology "an antibiotic producing mutant thereof" lacks enablement. The Examiner contends there is a lack of enablement because the phrase "an antibiotic producing mutant thereof" encompasses any mutant producing any antibiotic.

Applicants in answer to the 35 USC 112 first paragraph rejection of claims 23, 31, 33, 40, 41, 87, 99, and 104 as failing to comply with the enablement requirement have amended claims 23, 31, 33, 40, 41, 87, 99, and 104 by amending the phrase "an antibiotic producing mutant thereof" to "or an AA-896 antibiotic producing mutant thereof" to overcome the rejection of any mutant producing any antibiotic.

In further response, and in support of the enablement requirement applicants point the Examiner to page 18, lines 4-24 and page 19, lines 2-17 of the specification where mutant strains are produced and are further cultivated by procedures

described throughout the specification and in particular on page 25, lines 18-32 and page 26, lines 5-15 and in the examples.

Applicants believe they have provided enablement in the form of deposited strains and adequate description throughout the specification on how to produce mutants capable of producing AA-896 antibiotics. Applicants believe they have overcome the Examiner's rejection and respectfully ask the Examiner to reconsider and allow claims 23, 31, 33, 40, 41, 87, 99, and 104.

The Examiner has objected to claims 105-111 as being dependent upon a rejected base claim but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicants thank the Examiner for the statement that claims 105-111 would be allowable if rewritten in independent form including all of the limitations of the base claims and any intervening claims. Applicants have however amended claims 23, 31, 33, 40, 41, 99 and 104 to overcome the 35 USC 112 rejections as previously described and believe the objected to claims 105-111 are allowable.

With the present amendment, and for the reasons presented hereinabove, this application is believed to be in condition for allowance. The prompt sending of a notice thereof is believed to be in order and is respectfully solicited.

Respectfully submitted,



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